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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/853,079	05/09/2001	Steven G. Reed	210121.426C11	5270

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EXAMINER

BASKAR, PADMAVATHI

ART UNIT	PAPER NUMBER
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1645

DATE MAILED: 07/01/2002

7

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/853,079	Applicant(s) REED ET AL.	
	Examiner Padmavathi v Baskar	Art Unit 1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-36 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-36 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____ | 6) <input type="checkbox"/> Other: _____ |

RESTRICTION

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I Claims 1, 9 -10, 17 and 18 drawn to DNA, vector and host cell classified in class 536, subclass 23.7. Further election of invention required.
 - II. Claims 2-8, 12-16, 18 and 35-36 drawn to polypeptide and a kit classified in class 530, subclass 350. Further election of invention required.
 - III Claims 11 and 18 drawn to an antibody classified in class 530, subclass 388.6 Further election of invention required.
 - IV Claim 19 drawn to a method for inducing immune response classified in class 424, subclass 270.1. Further election of invention required.
 - V Claim 20 drawn to a method for the treatment of B.microti infection. classified in class 514, subclass 44. Further election of invention required.
 - VI Claims 21-22 drawn to a method of detecting B.microti infection using nucleic acid classified in class 435, subclass 6. Further election of invention required.
 - VII Claims 25-28 and 32-34 drawn to a method of detecting B.microti infection using protein antigen classified in class 435, subclass 7.22. Further election of invention required.
 - VIII Claims 23, 24 and 29-31 drawn to a method of detecting B.microti infection using antibody classified in class 435, subclass 7.22. Further election of invention required.
2. The inventions are distinct, each from the other because of the following reasons:

Group I is directed to DNA, which consists of nucleic acids. Groups II is directed polypeptides, which are made of amino acids; Invention III is drawn to an antibody and is

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distinct from Inventions I-II since it has an inherent affinity, avidity, and specificity that DNA or a simple protein is not capable of expressing. These products are different to each other structurally, biochemically and functionally.

Groups IV-VIII are different methods utilizing different products with different structure and biological properties. Inventions VI-VIII are drawn to different methods detecting of B. microti infections utilizing different biological reagents such as nucleic acids, proteins, and antibodies respectively. Inventions IV-V are drawn to methods for inducing immune response and treatment of B. microti infection utilizing different products namely proteins, nucleic acids and antibodies. Thus Inventions IV, V, VI, VII and VIII are different methods using different biological reagents, different method steps which result in different outcome.

3. Invention II is related to inventions IV, V, and VII as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the protein of Group II can be used in immunoaffinity chromatography methods for purifying antibodies and need not be used in the inventions IV, V, and VII.

4. Invention I is related to inventions IV, V and VI as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the nucleic acid of Group I can be used to make probes for using it in vitro hybridization and need not be used in the inventions IV, V and VI

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5. Invention III is related to inventions IV, V and VIII as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the antibody of Group III can be used in immunoaffinity chromatography for purifying antigens and need not be used in the inventions IV V and VIII

Distinct inventions

6. Although there are no provisions under the section for "Relation of Inventions" in MPEP 806.05 for inventive groups that are directed to different products; restriction is deemed proper because these products appear to constitute patentably distinct inventions for the following reasons.

Groups I- VIII contain claims (1-36) reciting a Markush group containing a plurality of disclosed patentably distinct inventions with distinct SEQ.ID.NOS. Applicant is advised to elect one SEQ.ID.NO. If applicant elects a polypeptide comprising epitopes, then applicant is required to identify the epitopes with specific amino acid but not a generalized formula as recited in claim 3. Applicant is required under 35 U.S.C. 121 to elect a single disclosed SEQ.ID.NO. If applicant elects inventions IV or V then applicant is advised to elect either polypeptide or polynucleotides or antibodies and identify the single disclosed SEQ.ID.NO.

7. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their separate classification and their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

8. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species

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to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

9. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

10. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Padmavathi v Baskar whose telephone number is (703) 308-8886. The examiner can normally be reached on M-F (6:30A.M-4: 00 P.M.) First Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (703) 308-3909. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

P. Baskar Ph.D.
6/27/02


LYNETTE R. F. SMITH
SUPERVISORY PATENT EXAMINER
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